UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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MEMORANDUM:

Subject: Occupational and Residential Exposure Assessment for the Proposed New Use of Zinc Pyrithione (ZPT) in Velox Plus Antifouling Paint

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EXECUTIVE SUMMARY

Velox Plus is proposed for use as an antifouling paint and it contains 13.3% zinc pyrithione (ZPT) as the active ingredient. It is formulated to adhere to high wear underwater drivetrain surfaces such as propellers, sail and stern drives and trim tabs. It is not ablative or self polishing and it not intended for use on hulls. It has a coverage rate of 450 feet per gallon.

Toxicological Endpoints Used for Risk Assessment

Dermal and inhalation exposures to ZPT are anticipated during the application of Velox Plus paint. The following Points of Departure (PODs) were selected for these exposures:

- A dermal NOAEL of 15 mg/kg/day from a dermal developmental toxicity study in rats during which maternal effects such limited use of hindlimbs and decreased body weight were observed with a LOAEL of 30 mg/kg/day. This NOAEL is applicable to dermal exposures of all durations.

- A Human Equivalent Concentration (HEC) of 0.58 mg/m^3 for eight hour time weighted average exposures is used for assessing inhalation exposures. This HEC was derived from the 90 day inhalation toxicity study NOAEL of 0.5 mg/m^3 and using a Regional Dose Deposition Ration of 1.57. This HEC is applicable to inhalation exposures of all durations.

The level of concern (i.e. the target MOE) for assessing dermal exposures is 100. The target MOE for inhalation exposures is 30. MOEs that are less than the target MOE indicate risks that are of concern.

Risk Summary

Velox Plus is intended for brush/roller applications by residential users. Residential painter exposures were assessed using two exposure studies of residential boat painters and estimated areas of the drivetrain components for three different types of boats. The dermal MOEs range from 9 to 1000 depending upon the type of boat painted and the amount of clothing and PPE worn. The dermal MOEs are above the target MOE of 100 for all of the boat types only when single layer clothing with gloves is worn. The inhalation MOEs are above the target MOE of 30 and are not of concern.

When used by commercial painters, Velox Plus can be applied using sprayers. Commercial painter exposures were assessed using a ship yard exposure study where antifouling paint was applied using airless sprayers. The dermal MOE is 1100 and is not of concern. The inhalation MOEs without respiratory protection range from 13 to 1400 and are of concern when the unit exposure data are considered from Trial B where the vessel being painted was enclosed. If PF10 half mask respirators are worn the MOEs range from 130 to 14,000 and are not of concern.

Risk Characterization

Although Velox Plus contains a higher concentration of ZPT (13.3 percent) than currently registered ZPT paints, which generally contain no more than 4.8 percent ZPT, the amount of ZPT used for painting drivetrain components with Velox Plus will be much less than the amount of ZPT that would be used for painting hull bottoms with the currently registered paints. This is because the surface area of drivetrain components is 10 to 50 times less than the surface area of hull bottoms.

The risks calculated from the proposed use of Velox Plus have a number of uncertainties that are based on the exposure data and assumptions. These uncertainties are as follows:

- Because there are no exposure data available for the painting of the boat drivetrain (i.e. propellers, stern drives and trim tabs), the data from studies in which hull bottoms were painted were used as a surrogate for assessing residential painter exposures. Because the painting of hulls was primarily done with rollers, which tend to spatter more than brushes, this data might overestimate the exposures that might result from the painting of the drivetrain which would primarily use brushes.

- The data from the spray painting of hull bottoms of large vessels in shipyards was used as a surrogate for the commercial spray painting of pleasure boat drivetrains because no other data was available. It is also not known how many boat drivetrains would be painted in a day or if the drivetrains would be painted in conjunction with hull bottoms.

- The lower arms and legs of the dermal dosimeters used in the Cruiser Uno study were not analyzed separately; therefore it is not possible to calculate the dermal exposures that would result from residential painters wearing short pants and short sleeve shirts.

1.0 INTRODUCTION

Velox Plus is proposed for use as an antifoulant paint and it contains 13.3% zinc pyrithione (ZPT) as the active ingredient. It is formulated to adhere to high wear underwater surfaces such as propellers, sail and stern drives and trim tabs. It is not ablative or self polishing and it not intended for use on hulls. It is intended for brush/roller applications by residential users or brush/roller and spray applications by commercial users. It has a coverage rate of 450 feet per gallon.

2.0 SUMMARY OF TOXICITY DATA

2.1 Acute Toxicity

The acute toxicity categories for ZPT are shown in Table 1. The most severe acute toxicity occurs from eye irritation (Toxicity Category I) and oral exposure (Toxicity Category II) while the remaining toxicities are in categories III and IV. ZPT tested negative for dermal sensitization.

Table 1 – ZPT Acute Toxicity Summary

Guideline Number	Study Type	MRID #	Result	Toxicity Category
870.1100	Acute Oral	42827901	LD50 = 630 mg/kg (M); 460 mg/kg (F)	II
870.1200	Acute Dermal	42146701	LD50 > 2000 mg/kg	III
§81-3	Acute Inhalation	42146703	LC50 >0.61 mg/L	III
870.2400	Primary Eye Irritation	42146702	severe irritant	I
870.2500	Primary Dermal Irritation	42146704	slight erythema and edema	IV
870.2600	Dermal Sensitization	43950201	No sensitization observed.	N/A

2.2 Toxicity Points of Departure Used for Risk Assessment

The points of departure (PODs) that were selected for use for occupational and residential risk assessment of ZPT are included in Table 2. The PODs for assessing dermal exposures are expressed as doses in mg/kg/day while the POD for inhalation exposure is expressed as a Human Equivalent Concentration (HEC) in mg/m^3. The HEC was calculated from the NOAEL of 0.5 mg/m^3 using a Regional Dose Deposition Ratio (RDDR) of 1.57.

The level of concern (i.e. the target MOE) for assessing dermal exposures is 100 which include the standard safety factors of 10X for interspecies extrapolation and 10X for intraspecies variation. The target MOE for inhalation exposures is 30 which include the factors of 3X for interspecies extrapolation and 10X for human variability. MOEs that are less than the target MOE indicate risks that are of concern.

Table 2 – ZPT PODs Used for Occupational and Residential Risk Assessment			
Exposure Scenario	**POD Used in Risk Assessment, UF**	**LOC for Risk Assessment**	**Study and Toxicological Endpoints**
Dermal, Short, Intermediate and Long Term	Dermal NOAEL = 15 mg/kg/day	MOE = 100 (residential) MOE = 100 (occupational)	Dermal Developmental Toxicity in Rats (MRID 46534001) Maternal LOAEL = 30 mg/kg/day, based on increased no. of dams with limited use of hindlimbs, shuffling gait, decreased body weight and body weight gain, and decreased food consumption.
Inhalation, Short, Intermediate, and Long Term	HEC* = 0.58 mg/m^3 (for 8 hour TWA)	MOE = 30 (residential) MOE = 30 (occupational)	Subchronic Inhalation Toxicity Study in Rats LOAEL = 0.0025 mg/L (2.5 mg/m^3) Based on clinical signs of toxicity, decreased activity, and increased lung weights. NOAEL = 0.5 mg/m3

*HEC = NOAEL * (6 hours study exposure/8 hours exposure) * RDDR (1.57)

Studies with ZPT were not available to address chronic toxicity and carcinogenicity. [Data on the carcinogenic potential of a related compound, sodium pyrithione, showed no evidence of carcinogenicity, and was classified as a Group D (not classifiable as to carcinogenicity) carcinogen by the Health Effects Division Carcinogenicity Peer Review Committee.] Therefore, a cancer risk assessment was not conducted since carcinogenic endpoints related to lifetime exposures of ZPT have not been identified.

2.3 FQPA Considerations

Previously, a Margin of Exposure of 300 had been recommended for residential exposures based on the application of a 3x database uncertainty factor for lack of neurotoxicity studies (US EPA, 2004). Although a subchronic neurotoxicity study was not submitted for ZPT, an acute neurotoxicity study was submitted and found to be acceptable, and the dermal developmental toxicity study reviewed recently also showed some indication of neurotoxic effects. Thus, these studies were felt to be adequate in characterizing the doses at which neurotoxic effects of ZPT start to appear. Thus, the 3x database uncertainty factor can be removed for residential assessments.

3.0 RESIDENTIAL EXPOSURE ASSESSMENT

3.1 Residential Painter Exposures

Residential painter exposures can occur during brush/roller application of Velox Plus Antifoulant paint. Both dermal and inhalation exposures are anticipated. These exposures were assessed using the following standard formulas.

Dermal Exposure

Residential handler dermal exposures are assessed using the following general formulas for exposure, dose and the margin of exposure (MOE).

Exposure (mg/day) = Unit Exposure (mg lb a.i.) * Amount a.i. handled (lb)

Dose (mg/kg/day) = Exposure (mg/day) / Body Weight (kg)

MOE (unitless) = NOAEL or LOAEL (mg/kg/day) / Dose (mg/kg/day)

Inhalation Exposure

Inhalation exposures are assessed using a different approach because the inhalation endpoint was based on an inhalation toxicity study and was expressed as a human equivalent concentration (HEC) for an eight hour exposure. This approach uses the following formula:

$$MOE = HEC\ (mg/m^3) / 8\ Hour\ TWA\ (mg/m^3)$$

Where:

MOE	=	Margin of Exposure
HEC	=	Human Equivalent Concentration
TWA	=	Time Weighted Average Air Concentration

3.2 Residential Painter Exposure Data

In the previous assessments of ZPT for the RED, PHED data and a literature study (Garrod, 2000) submitted by the registrant were used to assess exposures to residential boat painters. Since that time, the registrant has submitted MRID 465118-01 (Anderson and Sherratt, 2005) which evaluated exposures of amateur boat painters and is more representative than the PHED data. This study was reviewed by AD and the dermal data, which were based on copper oxide, are considered to be valid for use as generic data in this risk assessment. However, the inhalation data from the same study are not considered to be valid for use as generic data because they were based on trimethylbenzene (TMB) which has a vapor pressure of 1 mm @ 56 F and is not representative of exposures that might arise from ZPT which is non-volatile at ambient temperatures. Therefore, the Garrod study is retained for use in assessing inhalation exposure because it measured copper which is also non-volatile at ambient temperatures. Summaries of these two studies are included below:

MRID 465118-01 - Cruiser Uno: Determination of Dermal and Inhalation Exposure to Hazardous Substances during Amateur Use of Yacht Anti-Fouling Coatings, (Anderson and Sherratt, 2005)

The objective of this study was to quantify dermal exposure to copper oxide and inhalation exposures to tri-methyl-benzene (TMB) during the brush and roller application of Cruiser Uno antifouling paint to sail boats. Cruiser Uno paint contains copper oxide (26.5% to 35.5%) and has an advertized coverage of 350 ft^2/gallon when applied by brush. This study was conducted in March 2004 at a marina in Scotland using 15 amateur boat painters who painted 13 sailboats using brushes and rollers. One monitoring event was conducted inside a shed with natural ventilation (open doors) and the remaining monitoring events were conducted outdoors at various locations around the marina.

Dermal exposures to copper were monitored using inner and outer whole body dosimeters (including an outer hood), inner cotton gloves, outer nitrile gloves, and face/neck wipes.

The samples were collected, handled and analyzed in accordance with validated methods as described in the study report. The dermal dosimeter samples were extracted using concentrated nitric acid and copper was quantified using ICP-AES with an LOQ of 0.05 mg/liter. Because the concentrated nitric acid caused spontaneous combustion and loss of the first six nitrile glove samples, a solution of 50% nitric acid was used for the remaining glove samples and testing was done to verify that this would not invalidate the method. Laboratory fortification, field fortification and control blank samples were prepared and handled in the same manner as the field samples. The recoveries for the laboratory fortified copper samples were in the range of 90 to 110 percent with low variability. The recoveries for the copper field samples ranged from 57 to 120 percent and were of greater variability. The control samples contained no detectable copper.

The dermal exposure values were corrected for field fortification recoveries of 63.3% for the hood, face wipes and outer dosimeter suits, 57.1% for the inner dosimeter suits and 75 % for the inner cotton gloves. The nitrile glove samples were not corrected for field recovery because the recovery was greater than 100%. The inhalation exposure values were corrected for the laboratory recovery of 87.2% because the field recovery samples were invalid.

The dermal unit exposure values are summarized in Table 3. The unit exposures (mg cu/lb cu handled) were highest in the upper part of the outer dosimeter (mean = 323), the outer gloves (mean = 276) and bottom half of the outer dosimeter (mean = 144). The face wipe (mean 1.4) and the hood (mean = 35.4) were much lower. The exposures are also much lower if only the inner dosimeter and/or the inner glove values are considered. Since the lower arms and legs of the dermal dosimeters were not analyzed separately; it is not possible to calculate the dermal exposures that would result from residential painters wearing short pants and short sleeve shirts.

Table 3 – Dermal Exposures to Copper Measured During Brush/Roller Application of Antifoulant Paint (Cruiser Uno Study)						
Clothing and PPE Worn	**N**	**Min**	**GM**	**Mean ± SD**	**90th Percentile**	**Max**
Dermal Unit Exposure (mg copper/lb copper handled)						
No clothing, no gloves [Sum of all dermal samples]	9	515	763	820 ± 345	1295	1432
No clothing, gloves [sum of all dermal samples except outer gloves]	14	81	425	505 ± 322	1029	1082
Long-sleeved shirt, long pants, no gloves [Inner Suit + hood + outer gloves + inner gloves]	9	42.5	265	312 ± 136	456	475
Long-sleeved shirt, long pants, gloves [Inner Suit + hood + inner gloves]	14	2.7	22	41 ± 43	102	125

Note - The inner suit includes the upper and lower portions.

Potential Exposure of Amateurs (Consumers) through Painting Wood Preservative and Antifoulant Preparations, (Garrod, 2000)

The objective of this study was to quantify dermal and inhalation exposures during the painting of surfaces using wood preservatives, masonry treatments and antifoulants. A total of 25 monitoring units were collected and 10 of monitoring units involved the application of antifoulant paints, which contained copper. These paints were applied to sail boats by 9 amateur painters who generally applied one coat using a brush and/or roller (one painter applied two coats and was monitored twice). One monitoring event was conducted indoors and the remaining monitoring events were conducted outdoors.

Dermal exposures to copper were monitored using 6 patches affixed to the outside of the work clothing, cotton gloves and socks. Because of the uncertainties regarding extrapolation of the results from the small areas sampled by the patches to the corresponding body parts, the dermal data from this study are not considered further. Inhalation exposures were monitored using cellulose acetate filters held in a seven hole sampling device that was positioned in the breathing zone and operated at 2.1 liters per minute. The samples were digested using a mixture of sulphuric and nitric acid and the copper contents of the digest were analyzed quantatively using ICP-AES with a limit of detection was 0.2 ug/sample. Details regarding quality control samples were not provided in the article, however, the authors did indicate that "recoveries from the spiked sampling media ranged from 92 to 99 percent".

The exposure values are summarized in Table 4. According to the study author, copper was detected on only five of the ten samples collected and the air concentrations ranged from 0.03 to 0.11 mg/m^3. It is not clear what criteria were used for assigning non-detect values to the air sample results because given the LOD of 0.2 ug per sample, the pump flow rate of 2.1 liters per minute, the LOD in terms of air concentration would have ranged from 0.001 mg/m^3 for the 112 minute sample to 0.003 mg/m^3 for the 35 minute sample which are all lower than the lowest reported result of 0.03 mg/m^3.

Table 4 – Inhalation Exposures to Copper Measured During Brush/Roller Application of Antifoulant Paint (Garrod Study)						
Units	**N**	**Min**	**GM**	**Mean ± SD**	**90th Percentile**	**Max**
Air Concentration[A] (mg cu/m^3)	10	0.001	0.006	0.023 ± 0.035	0.056	0.11
Sample Duration (minutes)		35	78	82 ± 23	106	112
8 Hour TWA[B] (mg/m^3)		0.0002	0.0009	0.0046 ± 0.0076	0.012	0.024
A. Air Concentration (mg/m^3) = LOD (0.2 ug) / [Sample Time (minutes) * Pump Flowrate (2.) liter per minute)] B. 8 Hour TWA (mg/m^3) = [Air Concentration (mg/m^3) * (Sample Duration (minutes)] / 480 minutes						

3.3 Residential Painter Exposure Assumptions

The surface area painted is a key assumption and is based on MRID 480604-11 (STTA, 2010) which includes an analysis of the surface areas for the drive train components that would be painted with Velox Plus. These components include propellers, stern drives and trim tabs are found on larger boats that have inboard engines. Most motorboats less than 18 feet in length will not need Velox Plus treatment because they have outboard engines with propellers and stern drives that can be raised above the water when not in use. An analysis was therefore conducted for one sailboat type (Elan 31) and three motorboat types (Lancer 20, Cranchi SL 27 Single Engine and Cranchi SL 27 Twin Engine. Based on these boat types the following surface areas were estimated:

- Elan 31 Sailboat with a Volvo D1-20 engine – 3.5 square feet. This sailboat is considered a worst case example of a DIY sailboat because it is 30.8 feet which is large for a DIY painter, it has a sail drive while most sailboats have only a shaft and a propeller and it has an engine that is fairly large.
- Chris Craft Lancer 20 MotorBoat with a Volvo 4.3 GXi gasoline engine – 9.0 square feet. This boat is 20 feet long and it has a 225 HP stern drive engine with a single or dual prop. The area for the dual prop configuration was used. The area of two 9" X 12" trim tabs was also included.
- Cranchi SL 27 Motorboat with a Volvo D4-260/DP diesel engine – 11.5 square feet. This boat is 28.1 feet long and it has one 260 HP stern drive engine with two propellers. The area of two 9" X 18" trim tabs is also included.
- Cranchi SL 27 Motorboat with two Volvo D4-225/DP engines – 18.6 square feet This boat is the same as above except that it has two engines with two propellers each.

In addition to the area painted, the following assumptions were used:

- The paint contains 1.44 lbs ZPT per gallon based upon the proposed ZPT content (13.3 percent) and paint density (10.8 lbs/gallon).
- The amount of a.i. applied per coat is based on the amount of paint used and a ZPT content of 1.1 lb a.i. per gallon of paint.
- The number of coats applied per day is 2. This is based on the recommended number of coats (2 to 3) and a recoat time of 3 hours @ 70 F.
- The body weight of an adult handler is 60 kg for dermal exposures.
- Single Layer Clothing includes a long sleeve shirt and long pants.

3.4 Residential Painter Risk Summary

The dermal risk estimates (i.e. MOEs) for residential painters are summarized in Table 5 and the inhalation MOEs are summarized in Table 6. The dermal MOEs range from 9 to 1000 depending upon the type of boat painted and the amount of clothing and PPE worn. The dermal MOEs are above 100 for all of the boat types only when single layer clothing with gloves is worn. The inhalation MOEs are above the target MOE of 30 and are not of concern.

Table 5 - Dermal MOEs for Residential Painters Using Velox Antifoulant Paint

Exposure Scenario (Unit Exposure[A])	Boat Type	Area Painted per Coat[B] (ft^2)	Amount a.i. Handled[C] (lb/day)	Daily Dose[D] (mg/kg/day)	Dermal MOE[E]
No Clothing, No Gloves (820 mg/lb a.i.)	Sailboat Elan 31	3.5	0.022	0.30	50
	Motorboat Lancer 20	9.0	0.058	0.79	**19**
	Cranchi SL 27 Single Engine	11.5	0.074	1.01	**15**
	Cranchi SL 27 Twin Engine	18.6	0.118	1.61	**9**
No Clothing with Gloves (505 mg/lb a.i.)				0.19	79
				0.49	**31**
				0.62	**24**
				0.99	**15**
Single Layer Clothing and No Gloves (312 mg/lb a.i.)				0.11	140
				0.30	50
				0.38	**39**
				0.61	**25**
Single Layer Clothing with Gloves (41 mg/lb a.i.)				0.015	1000
				0.040	375
				0.051	290
				0.081	180

A. Unit Exposures are the mean values from the Cruiser Uno Study (MRID 465118-01)
B. Area Painted = Based on information given in STTA, 2010 (MRID 480604-11).
C. Amount a.i. Handled = [Area Painted Per Coat (ft^2) / Paint Coverage (450ft^2/gallon)] * 1.44 lb a.i. /gal * Number of Coats (2).
D. Dermal Dose (mg/kg/day) = [Dermal Unit Exposure (mg/lb a.i.) x Amount a.i. Handled (lb)] / BW (60 kg).
E. Dermal MOE = NOAEL (15 mg/kg/day) / Dermal dose (mg/kg/day).

***MOEs highlighted in bold font are less than the target MOE of 100 and indicate risks of concern.**

Table 6 – Inhalation MOEs for Residential Handlers of Velox Antifoulant Paint

Exposure Statistic	Copper 8 Hour TWA[A] (ug/m^3)	ZPT Adjusted 8 hour TWA[B] (ug/m^3)	Inhalation MOE[C]
Mean	4.6	0.14	4200
90th Percentile	12	0.40	1500
Maximum	24	0.51	1200

A. Time Weighted Average (TWA) from Garrod, 2000 where one coat of paint containing 7.4 to 29.8% copper was applied.
B. Adjusted 8 Hour TWA = Copper 8 Hour TWA *(Amount ZPT Handled/Amount Copper Handled)
C. Inhalation MOE = HEC(0.59 mg/m^3)/ [Adjusted 8 Hour TWA (ug/m^3) * 0.001 mg/ug]

***MOEs highlighted in bold font are less than the target MOE of 30 and indicate risks of concern.**

4.0 Commercial Painter Exposures

The Velox Plus label allows for spray application by commercial painters. Both dermal and inhalation exposures are anticipated. These exposures were assessed using the same formulas that were used for residential painter exposures.

4.1 Commercial Painter Exposure Data

Because are no other exposure data available, the exposures were assessed using the following shipyard painter study that was submitted by the registrant and reviewed in memo D311326 (US EPA, 2009). A summary of this study is included below.

MRID 467070-01, Assessment of Potential Inhalation and Dermal Exposure to Zinc Pyrithione During Outdoor Painting of Ship Hulls with Commercial Antifoulant Paint Containing Zinc Omadine, (Bookbinder, 2005)

The objective of this study was to quantify dermal and inhalation exposures during the spray application of antifouling paint to the hulls of commercial cargo and passenger ships. The ships were painted with an EPA registered paint formulation (#2693-187) that contained 3.80% zinc pyrithione and has a coverage of 130 ft^2 per gallon. Exposure monitoring was conducted at shipyards in Boston, Massachusetts (Trials A and D) and Freeport, Grand Bahama (Trials B and C). The Boston shipyard contained an excavated drydock and the Freeport shipyard contained a floating drydock. A total of 49 experienced workers in three job categories (pot man, spray man and line tender) participated in this study. The workers were monitored for 1-2 consecutive work cycles each over one or two test days and each work cycle consisted of the application of one coat of paint. One to three crews were monitored during each work cycle and each crew consisted of one to two members of each job category. Painting was done with airless spray guns without wands, fed by hoses from compressed air pumps operating at 3,500-4,500 psi. The work cycle durations ranged from 57 to 412 minutes and the surface area painted per person ranged from 5,000 to 13,800 ft^2. A summary of the conditions of each Trial is given in Table 7.

Table 7 – Shipyard Study Conditions

Trial	Ship Type	Date	Site Characteristics	Notes
A	Cruise Ship, 680' long, 91' beam, 20' draft	Nov-04	Plastic Sheeting with Some Gaps	Entire Hull below waterline was painted (27,600 ft^2) with two coats. One coat was applied each day. Each day was a work cycle. Workers wore work gloves with rubberized palms.
B	Mega Yacht, 171' long, 32' beam, 10' draft	Jan-05	Plastic Tenting with Small Exhaust Fan	Entire hull below waterline was painted (6400 ft^2) with three coats. One coat was on day one and two coats were applied on day two. Each coat was a work cycle. Workers wore nitrile gloves.
C	Cargo Ship, 90' long, 33' beam, 14' draft	Feb-05	No sheeting or tenting used	Same Yard as Trial B. Hull area = 5000 ft^2. Two coats were applied: one in the early afternoon and one in the evening. Each coat was a work cycle. Spray men also did line tending. Workers wore nitrile gloves.
D	Cruise Ship, 614' long, 92.5' beam, 20' draft	Apr-05	Plastic Sheeting with more gaps than Trial A.	Narrow band at waterline painted (6800 ft^2) with two coats over two days. Each coat was a work cycle. Workers wore nitrile gloves.

To measure dermal exposure, workers wore 100% polyester whole-body dosimeters under clean work clothes, covered by a Tyvek® hooded coverall. Workers also wore a pair of 100% polyester dosimeter gloves under either work gloves with rubberized palms (Trial A) or Ansell #92-600 gauntlet-style nitrile gloves (Trials B, C and D). Two 100 cm^2 100% polyester pads were used to monitor head and neck exposure. One pad was placed on the back of the work shirt, the other exposed on the front of his coverall. Inhalation exposure was monitored using 37-mm glass fiber filters in closed face cassettes positioned in the breathing zone. The flow rate of the sampling pump was calibrated to 1.5 liters per minute.

The samples were collected, handled and analyzed in accordance with validated methods as described in the study report. Field and laboratory fortification samples were generated at two levels (2X LOQ and 150X LOQ) for each matrix. The results of the field fortification samples indicated that the recoveries were generally above 90% and that the fortification levels matched the dosimeter residue levels. The head/neck patch residues; however, were orders of magnitude above the highest field fortification levels.

A summary of the dermal unit exposures is given in Table 8. The maximum dermal exposures occurred at Trial B where extremely high residues were measured on the head and neck pads which accounted for 90 to 98 percent of the dermal exposure. The head and neck was also a major contributor to the dermal exposures measured during Trial D when nitrile gloves were substituted for rubberized cotton gloves.

Table 8 – ZPT Shipyard Study Dermal Unit Exposures (mg/lb a.i.)

Trial	Job[2]	n	Whole Body Dosimeter		Gloves*		Head/Neck		Total Dermal	
			Range	AVG	Range	AVG	Range	AVG	Range	AVG
A	SM	6	0.1 –1.0	0.36	0.4 - 2.3	1.2	0.1 - 2.2	0.55	0.6 - 5.2	2.2
	LT	5	0.1 - 0.4	0.28	0.4 - 4.3	1.6	0.1 - 1.4	0.67	1.3 - 4.5	2.5
	PM	5	0.02 - 0.1	0.07	0.2 - 1.7	0.7	0.0 - 0.1	0.07	0.4 - 1.8	0.8
B	SM	6	0.5 - 3.3	1.3	0.05 - 0.21	0.12	0.9 – 10.8	5.5	2.0 - 12.3	6.9
	LT	6	0.2 - 0.7	0.46	0.01 - 0.12	0.04	0.04 -19.2	3.5	0.4 -19.6	4.0
	PM	3	0.1 - 0.2	0.13	0.0001- 0.002	0.001	0.02 - 0.03	0.021	0.1 - 0.2	0.15
C	SM	2	0.16,0.25	0.21	0.008, 0.038	0.023	1.2, 4.2	2.7	1.4, 4.4	2.9
	LT	2	0.10,0.28	0.19	0.002, 0.007	0.014	0.21, 0.24	0.22	0.33, 0.52	0.42
	PM	2	0.15,0.16	0.15	0.001, 0.003	0.006	0.08 – 0.11	0.10	0.23, 0.28	0.26
D	SM	4	0.04 - 0.16	0.09	0.08-0.31	0.19	0.3 - 3.3	1.5	0.6 - 3.4	1.8
	LT	3	0.01 - 0.26	0.10	0.005 - 0.019	0.014	0.02 - 0.28	0.11	0.07 - 0.30	0.22
	PM	5	0.003 - 0.01	0.006	0.001 - 0.004	0.003	0.013 - 0.52	0.030	0.02 - 0.06	0.039

Job: SM = Spray Man, LT = Line Tender, PM = Pol Man

*Workers wore rubberized palm cotton work gloves during Trial A and nitrile gloves during Trials B, C and D.

A summary of the inhalation exposures is given in Table 9. The inhalation exposures are expressed as time weighted average (TWA) air concentrations and include all of the samples collected on a worker for a workday. During Trials A and D, only one sample was collected per worker per day and during Trials B and C one or two samples per worker per day were collected. The TWA is calculated using the following formula:

$$TWA = \frac{(\text{Sample Time\#1} * \text{Air Concentration\#1}) + (\text{Sample Time\#2} * \text{Air Concentration\#2})}{(\text{Sample Time\#1} + \text{Sample Time\#2})}$$

To provide a basis for comparison to the HEC for ZPT, eight hour TWAs were also calculated by assuming that ZPT exposure occurred only during the time of sampling. The maximum inhalation exposures occurred during Trial B when the work area was enclosed with plastic sheeting to contain overspray.

Table 9 – ZPT Shipyard Study Inhalation Exposures (ug/m^3)

Trial	Job[2]	n	Sample Duration (Minutes)		ZPT TWA (ug/m^3)		ZPT 8 Hour TWA (ug/m^3)		Notes
			Range	AVG	Range	AVG	Range	AVG	
A	SM	6	254-375	299	22.2 – 120	75.7	12.5 – 72.9	46	
	LT	5	262-412	343	24.3 – 434	134	13.4 – 353	106	
	PM	5	267-365	325	13.9 – 23.1	18.5	10.1 – 14.0	12.3	
B	SM	4	101-130	116	3812-6333	5274	1033 – 1715	1263	Spray area
	LT	4	101-130	116	141-2074	756	51- 481	190	enclosed and
	PM	2	101,130	116	105,118	112	22.1,32.1	27.1	poorly ventilated.
C	SM	1	138	NA	396	NA	114	NA	
	LT	1	138	NA	56.7	NA	16.3	NA	
	PM	1	138	NA	50.4	NA	14.5	NA	
D	SM	4	157-203	182	21.7-95.5	68.5	8.3 - 36.2	26.0	
	LT	3	92-211	164	1.1-10.1	4.7	0.48 - 4.0	1.7	
	PM	5	151-214	187	0.7-1.7	1.1	0.24 - 0.70	0.45	

Job: **SM** = Spray Man, **LT** = Line Tender, **PM** = Pot Man

4.2 Commercial Painter Exposure and Dose Calculations

The boatyard worker's dermal exposures were calculated using the unit exposures for spraymen from the ZPT shipyard paint study along with assumptions of the daily a.i. amount handled. The inhalation exposures were calculated as unit 8 hour air concentrations for comparison to the HEC using the average 8 hour TWAs from the shipyard study and the corresponding amounts of ai handled.

4.3 Commercial Painter Exposure Assumptions

The following assumptions were used:

- A boatyard worker will paint the stern drive, trim tabs and propellers for one large boat (i.e. a Cranchi SL 27 Twin Engine) with two coats of Velox Plus in one work day.
- A PF10 respirator is a half face elastomeric respirator with appropriate cartridges and/or filters that provides a protection factor of 10 when the respirator is properly fitted to the user.

4.4 Commercial Painter Risk Summary

A summary of the dermal risk calculations is included in Table 10. The MOE of 1100 is not of concern. A summary of inhalation risk calculations is included in Table 11. The MOEs without respiratory protection range from 13 to 1400 and are of concern when the unit exposure data are considered from Trial B where the vessel being painted was enclosed. If PF10 half mask respirators are worn, the MOEs range from 130 to 14,000 and are not of concern.

Table 10 – Velox Commercial Boat Painters Dermal Risk Calculations					
Boat Type	**Amount Handled[A] (lb a.i./day)**	**Dermal Unit Exposure[B] (mg/lb a.i.)**	**Dermal Exposure[C] (mg/day)**	**Dermal Dose[D] (mg/kg/day)**	**Dermal MOE[E]**
Cranchi SL 27 Twin Engine	0.12	6.9	0.81	0.014	1100

A. Assuming two coats are applied to the propellers, stern drive and trim tabs.
B. Maximum Average Value for the Trial B sprayers from the shipyard study.
C. Dermal Exposure (mg/day) = Amount a.i. Handled (lb a.i./day) * Dermal Unit Exposure (mg/lb a.i.)
D. Dermal Dose (mg/kg/day) = Dermal Exposure (mg/day) / Body Weight (60 kg)
E. Dermal MOE = Dermal NOAEL (15 mg/kg/day) / Dermal Dose (mg/kg/day)

***MOEs highlighted in bold font are less than the target MOE of 100 and indicate risks of concern.**

Table 11 – Velox Commercial Boat Painters Inhalation Risk Calculations					
Trial	**ZPT Unit Exposure[A] (ug/m^3/lb a.i. handled)**	**Amount a.i. Handled During Velox Plus Painting[B]**	**Inhalation Exposure During Velox Plus Painting[C] (ug/m^3)**	**Inhalation MOE[D]**	
				No Respirator	**PF10 Respirator**
A	3.6	0.12 lb /day	0.43	1400	14000
B	367		44	13	130
C	14.5		1.7	350	3500
D	5.7		0.68	870	8700

A. The average values for the spraymen at each site.
B. Assuming two coats are applied to the propellers, stern drive and trim tabs.
C. Inhalation Exposure (ug/m3) = Unit Exposure (ug/m3/lb a.i. handled) * lb a.i. handled/day
D. Inhalation MOE = HEC(0.59 mg/m^3)/ [Inhalation Exposure (ug/m^3) * 0.001 ug/mg]

***MOEs highlighted in bold font are less than the target MOE of 30 and indicate risks of concern.**

5.0 RISK CHARACTERIZATION

Although Velox Plus contains a higher concentration of ZPT (13.3 percent) than currently registered ZPT paints, which generally contain no more than 4.8 percent ZPT, the amount of ZPT used for painting drivetrains with Velox Plus will be much less than the amount of ZPT that would be used for painting hull bottoms with the currently registered paints. This is because the surface area of drivetrain components is 10 to 50 times less than the surface area of hull bottoms. In addition, the risks calculated have a number of uncertainties that are based on the exposure data and assumptions. These uncertainties are as follows:

- Because there are no exposure data available for the painting of the boat drivetrain (i.e. propellers, stern drives and trim tabs), the data from the Cruiser Uno study in which hull bottoms were painted were used as a surrogate for assessing residential painter exposures. Because the painting of hulls was primarily done with rollers, which tend to spatter more than brushes, this data might overestimate the exposures that might result from the painting of the drivetrain which would primarily use brushes.

- The data from the spray painting of hull bottoms of large vessels was used as a surrogate for the commercial spray painting of pleasure boat drivetrains because no other data was available. It is also not known how many boat drivetrains would be painted in a day or if the drivetrains would be painted in conjunction with hull bottoms.

- The lower arms and legs of the dermal dosimeters used in the Cruiser Uno study were not analyzed separately; therefore it is not possible to calculate the dermal exposures that would result from residential painters wearing short pants and short sleeve shirts.

6.0 HUMAN STUDIES CONSIDERATIONS

All of the exposure studies mentioned in this risk assessment (Garrod, 2000, Anderson and Sherratt, 2005, and Bookbinder, 2005) have been cleared for use in risk assessment by the OPP ethics reviewers.

7.0 REFERENCES

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